UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

INTEGRA COMMUNITY CARE NETWORK, LLC, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	C.A. No. 24-cv-____ **EMERGENCY/EXPEDITED RELIEF REQUESTED**

COMPLAINT

Plaintiff Integra Community Care Network, LLC (Integra) brings this complaint against Defendants the Secretary of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS) and alleges as follows:

NATURE OF THE ACTION

1. Integra, a non-profit healthcare organization, seeks emergency injunctive—and ultimately permanent—relief to ensure continued operation of a healthcare program that provides services to thousands of senior citizens in Rhode Island. **Without immediate relief from the Court, this program will be forced to close effective January 1, 2025**.

2. Integra is an "accountable care organization" or ACO that participates in a government program called the Medicare Shared Savings Program or MSSP. As an ACO, Integra coordinates a full range of healthcare services for thousands of Medicare beneficiaries in Rhode Island. Special rules allow Integra to provide benefits and a broader range of services and care to

seniors than are allowed under the conventional Medicare system. This requires providing and accounting for healthcare in an entirely different way.

3. Integra has participated in MSSP and related Medicare ACO programs for a decade. Yet irrationally and contrary to law, CMS recently denied Integra's MSSP renewal application, ejecting Integra and its patients from MSSP effective January 1, 2025. This rejection was not the result of a policy issue or a substantive dispute about care or costs; Integra has been an excellent ACO, and the government is trying to expand the MSSP. Instead, the government's decision is a bureaucratic error applying a regulation that misunderstands a federal statute. Earlier this year, the Supreme Court made clear that agencies like CMS cannot rewrite or reinterpret federal statutes as CMS has purported to do here—and that federal courts must interpret and apply federal statutes when agencies err in this way. *See Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244, 2257 (2024). Integra now seeks relief from this Court to apply the law as written, allowing Integra to continue participating in MSSP.

4. The regulations in question—and CMS's error—are not especially complicated. By statute, an ACO must "have at least 5,000 [] beneficiaries assigned to it … in order to be eligible to participate in the ACO program." 42 U.S.C. § 1395jjj(b)(2). There is no dispute and no question that Integra meets this. By CMS's own estimate, Integra is expected to have 5,994 Medicare beneficiaries participating in its ACO in 2025—far more than the 5,000 minimum. Nor is there any dispute that Integra has more than 5,000 beneficiaries now and when it filed its application to continue participating in MSSP.

5. CMS instead based its decision on a regulation that "deems" an ACO to have satisfied the 5,000 minimum if 5,000 or more beneficiaries "are historically assigned to the ACO participants" for each of the preceding three years (here, 2022, 2023, and 2024). 42 C.F.R.

§ 425.110(a)(2). And CMS then concluded that ACOs can participate *only if* they meet CMS's deeming rule interpreting Congress's standard, whether or not they meet the standard that Congress set out.

6. Based on CMS's calculations,[1] Integra would have 5,994 beneficiaries in 2025 and had an estimated 5,994 in 2024 and 6,280 in 2023. But, according to CMS, Integra had only 4,863 for 2022. Because of this purported 137-patient shortfall in 2022, CMS claimed that Integra was ineligible to participate in MSSP in 2025, and its participation would terminate as of January 1, 2025. In other words, CMS took the position that its more restrictive deeming rule fully replaces the statutory requirement that an ACO "shall have" 5,000 assigned beneficiaries with a requirement that an ACO *have had* 5,000 beneficiaries in each of the three preceding years.

7. Integra promptly requested further review within CMS. Despite those efforts, CMS has yet to render a further decision, providing only vague assurances that one was forthcoming. For the reasons set out below, it is critical to both Integra and the Medicare patients it serves to confirm whether it can participate in MSSP prior to January 1, 2025.

8. Termination of Integra's participation in MSSP poses an existential threat to Integra and the accountable care it offers to thousands of Rhode Island patients. If Integra cannot participate in MSSP as of January 1, 2025, it will be forced to immediately stop many of the ACO services that it currently offers. It will also be forced to wind down any remaining programs in light of the massive budget shortfall it faces if it cannot participate in MSSP. Integra will also likely experience physician exoduses, as physicians too depend on the healthcare and administrative services and cost-savings an ACO provides. And, worst of all, Rhode Island patients

[1] To be clear, Integra disagrees with CMS's calculation, but its request for relief does not turn on this issue, as all sides agree that Integra has at least 5,000 beneficiaries assigned to it.

will suffer. They face the immediate or imminent loss of programs that Integra offers; they will lose access to the care coordination and assistance they currently have. Integra explained all of these risks to CMS—which has still not made a decision on whether to reverse its denial of Integra's renewal application.

9. Judicial review is critical. CMS premised its denial of Integra's application on the untenable position that a CMS regulation overrides the statutory minimum eligibility requirements. CMS has not shown any sign of changing its position—and, if anything, it has suggested that it *cannot* change its mind. But as the Supreme Court made clear again earlier this year, a regulation cannot supplant clear statutory text. CMS's denial of Integra's renewal application is straightforwardly unlawful, and this Court should say so. Integra, its providers, and its patients need urgent relief from CMS's unlawful denial.

PARTIES

10. Plaintiff Integra is a non-profit limited liability company with its principal place of business at 171 Service Avenue, Warwick, Rhode Island, 02886.

11. Defendant Xavier Becerra is sued in his official capacity only as Secretary of Health and Human Services. The Secretary of Health and Human Services is the official charged by law with administering the Medicare Act and the Medicare Shared Savings Program. The Secretary is the official against whom a Medicare Act claim is to be brought. *See* 42 U.S.C. §§ 405(g), 1395ii.

12. Defendant the Centers for Medicare & Medicaid Services is the federal agency tasked with the administering the Medicare Shared Savings Program.

JURISDICTION AND VENUE

13. This Court has jurisdiction under 42 U.S.C. §§ 1395ff, 1395jjj, 405(g), 1395ii, 28 U.S.C. § 1331 (federal question), and 28 U.S.C. § 1361 (mandamus).

14. Venue lies in this judicial district pursuant to 42 U.S.C. § 405(g) and 28 U.S.C. § 1391(e) because Integra has its principal place of business in this District.

FACTUAL ALLEGATIONS

A. The Medicare Shared Savings Program

15. Through the Patient Protection and Affordable Care Act, Congress established the Medicare Shared Savings Program, a voluntary program that encourages healthcare providers to collaborate to deliver coordinated, high-quality care to Medicare beneficiaries and to reduce Medicare spending. *See* 42 U.S.C. § 1395jjj(a)(1); CMS, *About the Program*, (Sept. 10, 2024), https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/about. The program is administered by defendant CMS, a federal agency within the Department of Health and Human Services.

16. Under MSSP, Medicare providers and suppliers participate in an ACO. *See* 42 U.S.C. § 1395jjj(a)(1). An ACO is a group of healthcare providers that work together to improve the quality and reduce the cost of care for a specific patient population (in the case of MSSP, for Medicare beneficiaries). ACO participating providers then share responsibility for the quality, cost, and coordination of care for their patients.

17. After forming an ACO, the ACO applies to CMS to participate in MSSP and agrees to be accountable for the healthcare quality and cost for an assigned Medicare beneficiary population. *See id.* § 1395jjj(b)(2)(D); CMS, *supra* ¶ 15.

18. To incentivize ACOs to deliver this high-quality and cost-conscious care, MSSP includes a structure through which the ACO obtains a portion of the savings it brings to Medicare. *See* 42 U.S.C. § 1395jjj(d). CMS continues to pay providers for services according to the applicable rates for fee-for-service providers in traditional Medicare. *See id.* CMS must then calculate the "estimated average per capita Medicare expenditures in a year, adjusted for

beneficiary characteristics under the ACO and" a "benchmark" for the ACO—i.e., the ACO's estimated expenditures for Medicare Part A (generally hospital) and Part B (generally physician) services for its assigned Medicare beneficiaries. *Id.* § 1395jjj(d)(2). And it then provides the ACO with a percentage of the savings (or losses under certain ACO arrangements). *Id.* § 1395jjj(d)(2); *see generally* 42 C.F.R. § 425.600 *et seq.*

19. ACOs must satisfy certain statutory eligibility criteria in order to participate. *See* 42 U.S.C. § 1395jjj(b). The ACO must enter an agreement with CMS to participate for at least three years, be willing "to become accountable for the quality, cost, and overall care" of its assigned Medicare beneficiaries, and have certain legal, leadership, management, and reporting structures. *Id.* § 1395jjj(b)(2)(A)-(C), (E)-(H).

20. The ACO must include enough primary care providers to serve the Medicare beneficiaries assigned to it. 42 U.S.C. § 1395jjj(b)(2)(D). And, as described above, the ACO must meet a minimum beneficiary requirement: "the ACO shall have at least 5,000 [] beneficiaries assigned to it … in order to be eligible to participate in the ACO program." *Id.* § 1395jjj(b)(2)(D).

21. CMS regulations include this same 5,000-beneficiary-minimum eligibility requirement. *See* 42 C.F.R. § 425.110(a). By CMS regulation, the "ACO must have at least 5,000 assigned beneficiaries." *Id.* § 425.110(a)(1). After subsection (a)(1) recites the same 5,000-beneficiary test as found in the statute, subsection (a)(2) of CMS's regulations then adds a second provision about deeming: "CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries … if 5,000 or more beneficiaries are historically assigned to the ACO participants" for each of the three preceding years. *Id.* § 425.110(a)(2).

B. Integra and its Accountable Care Organization

22. Founded in 2014, Integra is an ACO that serves Rhode Island patients. It was established with the express intention of serving as an ACO for Rhode Island's Medicare population.

23. Care New England Health System (Care New England)—a non-profit health system comprised of several Rhode Island Hospitals and affiliated providers—established Integra after performing a needs assessment of its health system. It found that Rhode Island's substantial geriatric population had several deficits in accessing high-quality care. Care New England's needs assessment showed patients, particularly geriatric patients, disproportionately found themselves in hospitals or nursing homes facing acute or critical situations that could potentially have been prevented by enhancing access to and coordination of care outside of these facilities.

24. Care New England believed that Rhode Island's geriatric population could be better served and resolved to pursue a path toward improving geriatrics' care. The underlying commitment to improving the cost, quality, and satisfaction with care drove the team to create the Integra network.

25. Concurrently, CNE leadership partnered with local payors and a large group of primary care practices in the largest independent practice association in the state to collaborate on creating innovative models of care, particularly for older adults in Medicare and Medicare Advantage.

26. The overarching mission was to improve the quality of care and the coordination of care across a fragmented health care landscape. Integra is one of the first ACOs in Rhode Island and has been prominent in state-guided care innovation work, committed to cost growth target efforts with the Office of the Health Insurance Commissioner, and a consistent voice in improving the cost and quality of healthcare for Rhode Island residents.

27. Shortly after Integra's founding, Integra's then-Chief Clinical Officer defined Integra's mission as delivering the right care in the right way at the right time and in the right place, a tried but true definition of care coordination and an accountable care organization's mission. The care management model built at Integra then is in place now, and Integra continues to live by this motto.

28. Care New England thus established Integra as an ACO to participate in the Medicare Shared Savings Program and related Medicare ACO programs. The Integra ACO would then have the tools necessary to work with patients across healthcare providers and services and provide access to differentiated services that could meet their needs in new ways while also reducing the cost burden of healthcare for Rhode Islanders. The entire health system is committed to changing care delivery patterns to foster coordination and improved effectiveness of the care journey and remains thus committed today in 2024.

29. Integra has now become a leading ACO. Integra brings together primary care physicians, specialist physicians, nurses, social workers, pharmacists, and community health workers to provide comprehensive health services to patients. Integra's network includes providers employed by Care New England and providers in the community who enter agreements to participate in the ACO. Patients with a primary care physician that participates in Integra's ACO are automatically eligible for the ACO services Integra provides.

30. For patients, Integra provides wraparound patient support and coordination of care. It can arrange transportation to medical appointments, connect patients to community resources, and provide health education to help manage chronic conditions like diabetes, asthma, and COPD. Integra clinicians perform home visits and provide after-hours clinical support to older adults and those with chronic illnesses, extending the reach and scope of services that a primary care practice

offers. Integra staff meet with patients who have been admitted to hospitals to support care coordination and to help hospital-based care management teams with safe and effective transitions of care.

31. For example, when a patient is discharged from the hospital, Integra ensures the patient obtains a follow-up appointment with his or her primary care physician or other necessary physician, often not just by booking the appointment at the time of discharge, but also by calling a few days later to ensure that they have a ride and that the time of the appointment will still work for the patient. Patients outside the Integra ACO must coordinate appropriate follow-up care themselves—which often leads to such care not being arranged, appropriate follow-up not being performed, and the patient experiencing worse outcomes, including a return to the hospital. These services are essential for patients with multiple chronic illnesses or behavioral health needs who would not be able to access the healthcare they need without the support of Integra's teams. Integra's services can thus reduce the extent to which the most complex patients experience negative outcomes because of the burdens inherent in navigating the healthcare system without the support of Integra's ACO.

32. ACOs like Integra can improve patient care while achieving cost savings through a variety of services. ACOs can better coordinate a patient's care by providing appointment-scheduling, reminders, and follow-ups. ACOs can direct patients to and schedule appointments with necessary specialists. ACOs can communicate with patients after a hospital stay to ensure they have necessary medications and follow-up appointments. All of these coordination services make healthcare far more accessible—especially for those patients with complex needs. And when patients can more easily access care, they experience better outcomes.

33. ACOs also offer more complex healthcare services. Integra, for example, offers an in-home paramedic service. A primary care provider in Integra's ACO can contact Integra to dispatch a paramedic to a patient's home 24 hours a day. These visits can often save patients the challenges of admission to the emergency department or hospital inpatient unit, with care under the supervision of their own doctor. By reducing emergency room visits and hospitalizations, Integra can thus improve patient outcomes while also reducing costs. Integra also offers patients healthcare and community resources as part of its wraparound approach to patient care. It can educate patients on their conditions to help them manage those conditions. And it can also assist patients with other aspects of life that may get in the way of seeking healthcare—like housing, financial insecurity, or transportation challenges.

34. In addition to assisting patients, the ACO structure also improves physicians' practices. Integra can eliminate many of the burdens of running a healthcare practice, like scheduling appointments, ensuring patients show up to appointments, responding more promptly to patient questions or concerns, and providing care services a physician's office is not equipped to provide on its own.

35. By taking a more holistic approach to patient care, ACOs like Integra improve the health of the patient populations they serve, ease the burdens on healthcare providers, and generate considerable cost-savings for Medicare. Integra's services for patients include (without limitation):

a. **Ambulatory care management:** Integra provides wraparound support and care coordination to ambulatory patients. Integra personnel serve as an extension of patients' primary care team to help them obtain and manage appointments and communicate with their care team effectively. The core skills of Integra's ambulatory care management teams include medication

education and management support, disease education, and caregiver support. It is well established that this leads to better health, patient satisfaction and reduced healthcare costs.

b. **Transitions of care:** Integra personnel coordinate and manage patients' transition from a hospital or skilled nursing facility back into the community. Integra manages details like ensuring the patient has their necessary medications and instructions and obtain follow-up appointments with their primary care provider.

c. **Integra at Home**. Integra can provide acute medical services in a patient's home. Nurse practitioners are available to see patients by phone or video. Integra can also dispatch community paramedics to a patient's home to provide emergency care. These in-home services can often prevent a patient from ending up in an emergency department or hospital. Integra at Home helps to honor patient choice and allow the management of both acute conditions and flare-ups of chronic disease. The team also includes social workers, pharmacists, and community health workers who ensure that all aspects of a patient's health and well-being are addressed.

d. **Resources**: Integra also provides access to educational and community resources. It can provide information regarding patients' healthcare, like resources about a patient's condition or on nursing facilities. It also provides access to community resources, including guides on housing, food resources, utilities, activities, mobility, finances, transportation, safety, legal issues, and social activities via robust partnerships with community-

based organizations. Integra's care management team is also trained and skilled in facilitating conversations about goals of care and patient preferences to support care plans that meet those preferences.

36. Integra's patient programs were designed particularly with Medicare beneficiaries in mind. The Medicare population includes more high-risk, complex patients, the types of patients who benefit enormously from having centralized and comprehensive assistance with their healthcare and other needs. Integra's team has been recognized for successfully reducing unnecessary and costly healthcare services, maximizing time at home for patients who otherwise would have frequent hospitalizations or skilled nursing facility stays. This work is especially important in older adults where there is abundant evidence that hospitalizations and transitions of care introduce the risk of functional decline, complications, and poor future health outcomes. Integra's commitment to older adults aging well in Rhode Island is a core mission, of which being an MSSP ACO is crucially important.

37. Participating in Integra's ACO also provides substantial benefit to physicians and other providers by easing their administrative burdens and improving patient care. Primary care physicians in particular rely on Integra to handle patient outreach, ensuring patients schedule and arrive at their appointments. Integra operates as an extension of the primary care provider's office, taking some of the burden off of the provider.

38. Integra also provides administrative services, including by providing contracts, tools, data, support programs, transparency, experience, and resources to physicians to help them manage and run their practices.

39. Integra provides actionable reporting primary care physicians and clinicians to help them identify patients who might benefit from added layers of support, and those who need outreach and appointments to address and close gaps in care.

40. Integra's navigators and nurses help busy primary care practices educate patients on the importance of making and keeping screening appointments. They also ensure that the primary care team sees and reviews test results as a result of screenings, helping to identify potential problems and improve the quality of care provided to their patients.

41. Integra has received substantial recognition for the quality of its services:

a. Integra has made multiple presentations to the Institute of Healthcare Improvement on its programs.

b. Integra has been a grantee of the West Health Institute every year since 2018 with various projects around improving the care of older adults and testing innovative models of care such as the Integra at Home program.

c. In 2020, Integra earned the second-highest quality score nationally in CMS's Next Generation ACO program, with a grade of 98.59 out of 100, exceeding the national average of 92.98.

d. In 2024 Integra was recognized by the American Cancer Society and a commercial payer partner for exceeding expectations in colon cancer screening.

e. Integra has been a subject matter expert and presenter in multiple meetings of the National Association of ACOs, including most recently in September of 2024.

42. The Medicare Shared Savings Program has been a resounding success. CMS estimates that MSSP generated more than $2.1 billion in savings for Medicare in 2023 alone.[2]

43. Integra is proud to have been a participant in MSSP and related Medicare ACO programs for ten years and looked forward to continuing its service for Rhode Island patients into 2025 and beyond. Integra thus applied to renew its participation in MSSP.

44. In light of the substantial success it experienced with its Medicare ACO services, Integra has grown significantly. In past years, Integra has served nearly 150,000 patients. As of December 2024, Integra serves nearly 11,000 Medicare beneficiaries, 46,000 Medicaid recipients, roughly 16,000 Medicare Advantage enrollees, and more than 12,000 commercially insured patients.

C. Integra's MSSP renewal application for 2025

45. Integra initially participated in the MSSP in 2014 before transitioning to participation in the Medicare Next Generation ACO model—CMS's then demonstration ACO program for high-performing ACOs capable of bearing greater risk.

46. Integra initially participated in the MSSP in 2014 before transitioning to participation in the Medicare Next Generation ACO (CMS's then-demonstration ACO program for high-performing ACOs capable of bearing greater risk).

47. In connection with the expiration of the Next Generation ACO program, in 2019 Integra applied to return to, and was accepted back into, the MSSP. Integra has thus provided services to thousands of Medicare beneficiaries through Medicare ACO programs for ten years.

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[2] CMS, *Medicare Shared Savings Program Continues to Deliver Meaningful Savings and High-Quality Health Care* (Oct. 29, 2024), https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-continues-deliver-meaningful-savings-and-high-quality-health-care

48. Under the MSSP, Integra provides ACO services to Medicare beneficiaries whose primary care physicians participate in Integra's ACO. When Integra's services result in savings for the Medicare program—by improving the quality of care, reducing unnecessary care, and improving patient outcomes—it receives a shared savings payment, which reflects a portion of the amount that it saved the Medicare program.

49. In May 2024, Integra began the process of applying to renew its participation in MSSP for 2025 for a five-year term. Integra finalized and submitted "phase 1" of the application on June 12, 2024, and submitted updates in response to CMS's standard requests for additional information throughout August and September 2024.

50. On October 17, 2024, CMS transmitted by email a "denial" of Integra's application. The denial email is attached as **Exhibit 1.** In the denial email, CMS stated that Integra's participation would be terminated as of December 31, 2024.

51. CMS gave a single reason for the denial. CMS asserted that Integra's ACO "has fewer than 5,000 assigned beneficiaries in one or more of the three benchmark years" and thus "does not meet the requirements of 42 CFR § 425.110":

Question	Deficiency Code	Deficiency Code Description
N/A	2025_RA_5k	Insufficient number of assigned beneficiaries: Your ACO has fewer than 5,000 assigned beneficiaries in one or more of the three benchmark years as calculated using the assignment methodology set forth in Part 425 subpart E. Thus, it does not meet the requirements of 42 CFR § 425.110.

Exhibit 1.

52. CMS's data showed that Integra would have substantially more than 5,000 beneficiaries—5,994—for 2025 and that it had more than 5,000 beneficiaries for 2023 and 2024.

But, according to CMS, a revised assignment of 4,863 beneficiaries to 2022 precluded Integra's eligibility to renew its application for 2025:

Integra Community Care Network, LLC.

Program Year: 2025

ACO Information

ACO ID	ACO TIN	Track
A4575	[redacted]	

Status

Agreement Status	Application Status	Re-Entering
Denied	Denied	Yes

Dates

Start Date	Agreement Period Start Date	Termination Date	Performance Year	Agreement Period
07/01/2019	01/01/2025	-	1	2

Agreement Details | Performance Year | Application Cycle | Documents | ACO Participants | SNF Affiliates | Contacts | Marketing | RM Generator

Application Cycle Filter

		Phase 1				Phase 2		
Phase	Participation Options Change Request	Phase 1 Applications	Phase 1 RFI-1	Phase 1 RFI-2	Phase 1 Final Disposition	Phase 2 Applications	Phase 2 RFI	Phase 2 Final Disposition
Application Type	-	Renewal Application	-	-	Renewal Application	-	-	-
Track		ENHANCED			ENHANCED			
Status	-	Pending	-	-	Denied	-	-	-
Prospective Assignment BY1 (2022) Beneficiary Estimate	-	-	6,294	3,437	-	-	-	-
Prospective Assignment BY2 (2023) Beneficiary Estimate	-	-	6,353	4,205	-	-	-	-
Prospective Assignment BY3 (2024) Beneficiary Estimate	-	-	6,341	6,216	-	-	-	-
Prospective Assignment PY 2025 Beneficiary Estimate	-	-	6,578	6,401	-	-	-	-
Retrospective Assignment BY1 (2022) Beneficiary Estimate	-	-	7,418	5,308	4,863	-	-	-
Retrospective Assignment BY2 (2023) Beneficiary Estimate	-	-	6,908	6,914	6,280	-	-	-
Retrospective Assignment BY3 (2024) Beneficiary Estimate	-	-	6,833	6,643	5,994	-	-	-
Retrospective Assignment PY 2025 Beneficiary Estimate	-	-	6,834	6,643	5,994	-	-	-
Cycle Start Date	08/21/2024	05/20/2024	07/10/2024	08/21/2024	10/17/2024	10/18/2024	11/07/2024	12/05/2024
Cycle End Date	09/05/2024	06/17/2024	08/01/2024	09/05/2024	10/17/2024	10/29/2024	11/18/2024	12/05/2024

See Exhibit 4 at 7.

53. That is, according to CMS, this newly identified shortfall of 137 patients in a retrospective assignment for 2022 establishes that Integra cannot demonstrate that it shall have at least 5,000 beneficiaries and is thus ineligible to participate in MSSP for 2025. Exhibit 1.

54. Integra timely requested a reconsideration review under 42 C.F.R. § 425.802. Integra's request for reconsideration review is attached at **Exhibit 2**. In its reconsideration review

request and supporting brief (attached hereto as **Exhibit 3**), Integra explained that CMS's denial of Integra's application was erroneous and unlawful.

55. CMS did not substantively oppose Integra's reasons for reconsideration; instead, it filed a brief on December 2, 2024 taking the position that Integra was precluded from administrative review by operation of 42 C.F.R. § 425.800. *See* **Exhibit 4**.

56. A decision from CMS is not immediately forthcoming. After inquiry by Integra, on December 12, 2024, CMS stated that the reconsideration official would not issue a decision until 30 days after December 6—i.e., not until January 5, 2025—after Integra's participation in MSSP ends.

57. On December 16, 2024, Integra requested that CMS expedite the reconsideration process or confirm that it would agree to continue Integra's participation in MSSP after January 1, 2025, through the time of the decision. Integra explained the immediate and irreparable harm that it would suffer if it is not eligible to participate in MSSP as of January 1, 2025. CMS responded, stating that the "review is underway and the Reconsideration Official will likely issue a recommendation in the very near future." Attached hereto as **Exhibit 5** is the email chain between Integra and CMS regarding the timing of CMS's decisions.

58. Despite its promise of a decision in the very near future, as of today, CMS has not issued a decision or provided further updates.

D. CMS's denial of Integra's MSSP renewal application is unlawful because Integra undisputedly has and will have at least 5,000 beneficiaries in 2025, satisfying the eligibility threshold set out in federal law.

59. CMS's denial of Integra's MSSP renewal application is unlawful. 42 U.S.C. § 1395jjj(b)(2)(D) sets a minimum eligibility requirement that the ACO shall have at least 5,000 beneficiaries. CMS's regulations first repeat the same standard. 42 C.F.R. § 425.110(a)(1). But then CMS's deeming regulation—which CMS has construed to somehow supplant the statutory

minimum with a three-year retrospective requirement—is contrary to the statute. CMS cannot lawfully use 42 C.F.R. § 423.110(a)(2) in this manner.

1. The statute and CMS regulation require only that an ACO "shall have" 5,000 beneficiaries.

60. The Medicare Act requires that, to be eligible for MSSP, an ACO "shall have at least 5,000 … beneficiaries assigned to it." 42 U.S.C. § 1395jjj(b)(2)(D).

61. CMS regulations impose the same requirement: "The ACO must have at least 5,000 assigned beneficiaries." 42 C.F.R. § 425.110(a)(1). As a regulation that parrots the statute, Section 425.110(a)(1) has the same meaning as the statute. *See, e.g.*, *N.H. Hampshire Hosp. Ass'n v. Azar*, 887 F.3d 62, 75 (1st Cir. 2018).

62. CMS determined that Integra will have an expected 5,994 beneficiaries assigned to it for 2025. Exhibit 1; Exhibit 4 at 7. Integra therefore satisfied the statutory eligibility criteria; Integra "shall have at least 5,000 … beneficiaries assigned to it" for 2025. 42 U.S.C. § 1395jjj(b)(2)(D).

63. The "best reading" of Section 1395jjj(b)(2)(D) is what it says plain on its face (*Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266 (2024)): an ACO is eligible for MSSP if it "shall have" 5,000 beneficiaries assigned to it. Here, Integra satisfied that requirement. CMS estimated that Integra "shall have" an estimated *5,994* beneficiaries assigned to it for 2025.

64. Because Integra satisfied the requisite eligibility requirement, CMS's denial—which rested only on Integra's alleged failure to have satisfied the 5,000-beneficiary minimum—is contrary to statute and to CMS's implementing regulation.

2. CMS's backward-looking deeming regulation cannot fully supplant the statutory 5,000 minimum.

65. Despite the clear statutory and regulatory language, CMS denied Integra's application for failing to satisfy the 5,000 minimum based on another regulatory provision.

66. Section 425.110(a)(2) provides that CMS will "deem[] an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries … if 5,000 or more beneficiaries are historically assigned to the ACO participants in each of the 3 benchmark years." 42 C.F.R. § 425.110(a)(2).

67. CMS determined that Integra had more than 5,000 beneficiaries assigned to it for 2023 and 2024 but that it had only 4,863—less than 5,000—assigned to it in 2022. Exhibit 1.

68. Specifically, CMS reached the following beneficiary assignment counts in its final disposition:

Year	CMS Final Disposition
2022	4,863
2023	6,280
2024	5,994
2025 (est.)	5,994

69. CMS then denied Integra's application for failing to satisfy the deeming rule of Section 425.110(a)(2). Indeed, CMS rested its denial squarely on Integra's failure to satisfy the deeming rule:

> Your ACO has fewer than 5,000 assigned beneficiaries in one or more of the three benchmark years as calculated using the assignment methodology set forth in Part 425 subpart E. Thus, it does not meet the requirements of 42 CFR § 425.110.

Exhibit 1.

70. CMS did not acknowledge its own determination that Integra would have 5,994 beneficiaries for 2025, nor did it acknowledge that Integra had more than 5,000 beneficiaries for 2023 and 2024 and an average assigned beneficiary count across the three benchmark years that was well in excess of 5,000 assigned beneficiaries. *See* Exhibit 1; Exhibit 4.

71. The position CMS espoused through its denial—that Section 425.110(a)(2) is the *only* way in which to ascertain whether an ACO "shall have at least 5,000 … beneficiaries assigned" to it—is contrary to statute.

72. The statutory eligibility requirement requires only that the ACO "shall have" 5,000 beneficiaries assigned to it. Had Congress intended to impose a requirement that was only backward-looking, it would have used very different language.

E. CMS's unlawful denial will cause severe irreparable harm to Integra, providers, and patients if not immediately enjoined.

73. CMS's denial of Integra's application is contrary to the statute and to its own regulation. If CMS's unlawful denial is left in place, Integra's participation in MSSP will terminate as of January 1, 2025, and it will wreak devastating irreparable harm on Integra, its providers, and the Rhode Island patients Integra serves. These immediate harms cannot be remedied were the Court to later reverse CMS's unlawful denial.

1. CMS's unlawful denial will cause severe irreparable harm to Integra starting January 1, 2025.

74. Integra will have to immediately reduce its programs because of waiver eliminations if it cannot participate in MSSP on January 1, 2025. That is because some of Integra's services can only lawfully be performed because Integra participates in MSSP.

75. Participating in MSSP provides waivers from the ordinary operation of certain Medicare restrictions so that ACO programs can operate as intended. *See* 42 U.S.C. § 1395jjj(X) (authorizing the Secretary to waive certain requirements "as may be necessary to carry out the provisions of this section").

76. For example, the Anti-Kickback Statute imposes criminal penalties on anyone who knowingly and willfully offers, pays, solicits, or receives remuneration to induce the referral of business under a federal healthcare program, unless a safe harbor applies. *See* 42 U.S.C. § 1320a-

7b(b). CMS has expressed concern that an ACO distributing shared savings payments among ACO participants or arranging for centralized electronic health record technology or engaging specialists in care coordination might implicate the Anti-Kickback Statute. *See* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66,726, 66,729 (Oct. 29, 2015). CMS thus provided a waiver from these requirements related to MSSP participation to avoid otherwise defeating an ACO's ability to deliver the savings the MSSP intended. 42 CFR §§ 1001.952(kk), 1001.952(hh).

77. As another example, the Stark Law generally prohibits physicians from making referrals for "designated health services" to entities with which the physician has a financial relationship, unless an exception applies. 42 U.S.C. § 1395nn. This would include physicians in an ACO arrangement. CMS thus promulgated a waiver—because the ACO structure can only operate in reliance on the waiver.

78. As another example, 42 U.S.C. § 1320a–7a(a)(5) prohibits offering or transferring remuneration to a Medicare or Medicaid beneficiary if it is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service payable by Medicare or a State health care program (including Medicaid). Absent a waiver, CMS recognized, that this could effectively defeat an ACO's operation. 80 Fed. Reg. at 66,729.

79. Through an ACO model, the ACO becomes accountable for the quality and cost of a patient's care. The ACO model by design addresses the potential incentive for providers to produce more units of healthcare to obtain payment. But the regular operation of these laws can impede the ACO's process by making its cost-saving and care-improving programs potentially unlawful. Because of the risk that these laws would undermine the effectiveness of an ACO and

thus the purpose of the MSSP, CMS prescribed waivers of these laws for ACO participants. *See* 80 Fed. Reg. at 66,742-66,743.

80. CMS has also included waivers of payment-related provisions that help an ACO perform its services. For example, under traditional Medicare, to reduce fraud and abuse, Medicare generally will not cover skilled nursing facility care unless it was preceded by a 3-day hospital stay (presumably, to ensure medical necessity for the nursing-home stay). CMS has provided a waiver of this payment rule for patients in an ACO participating in MSSP that allows patients to go directly to a skilled nursing facility with a stay shorter than three days in the hospital. *See* 42 C.F.R. § 425.612(a)(1). This is because the ACO is properly incentivized to manage the total cost of care and avoid unnecessary care. Yet the effect of CMS's decision to exclude Integra would be to force Rhode Island seniors into the hospital for at least three days in order to access any necessary nursing-home care.

81. If CMS's rejection of Integra's renewal application remains in place, starting on January 1, 2025, Integra will no longer be eligible for these crucial waivers. Without these waivers, Integra would face potential criminal or civil liability or non-payment for care if it were to continue certain operations. Integra's core programs that rely on these waivers—including care management, Integra at Home, the skilled nursing facility waiver program, the provision of transportation support, and programs that address other social drivers of health—would have to be wound down. This would deny patients access to these services.

82. Integra would also have to shut down the remainder of its programs likely within the first quarter of 2025. For any services that Integra can lawfully perform after January 1, 2025, it will suffer enormous financial losses to maintain those ACO services. That is because, when Integra budgets for the year, it includes the anticipated revenue from MSSP. Without this

anticipated revenue, Integra will face a budget shortfall of more than $1 million. Integra likely could not recover these financial losses from the government if it were to prevail on its claims that CMS's rejection of Integra's renewal application was unlawful.

83. Integra would also have to commence reductions in force. Integra cannot continue to pay staff for services that Integra can no longer offer. Integra would be unlikely to recoup its workforce if CMS's decision were later to be reversed, which means it could not return to offering the same service level quickly.

84. Integra would also likely lose the physician composition that makes it a successful ACO. If Integra is not permitted to participate in MSSP as of January 1, 2025, a number of physicians may attempt to terminate their participation in Integra's ACO. For physicians that need the ACO structure for their practice viability, they would likely withdraw from Integra's ACO and attempt to join another. These physicians could enter into multi-year agreements with a different ACO, such that Integra could not get them back if CMS's decision were later reversed. It is likely that half of Integra's network physicians could leave. It would take at least four to five years for Integra to recover those levels of participation, if it even remains viable and operating to be able to try to do so.

85. If CMS's rejection of Integra's MSSP application is left in place and Integra is not permitted to participate in MSSP as of January 1, 2025, Integra faces an immediate and existential threat to its ACO business. It risks irreparable reductions in force, irreparable losses of physicians, and unrecoverable financial losses for any efforts it undertakes to mitigate the serious detriments to patients of the loss of wraparound ACO services.

2. Reversing CMS's unlawful denial is in the public interest to avoid harms to patients and providers.

86. If CMS's unlawful denial remains in place, and Integra cannot participate in MSSP as of January 1, 2025, severe and irreparable harm will befall more than Integra. More importantly, the patients covered by Integra and the providers who participate in Integra's ACO will also suffer.

87. For providers who participate in Integra's ACO, they would immediately lose access to the services Integra provides that enhance their ability to care for patients and reduce administrative burdens. Integra provides a robust team-based model to backstop primary care services around the clock. Integra can only perform these services for physicians' offices because of CMS waivers or in anticipation of shared savings revenue that make these services financially feasible. If Integra is no longer participating in MSSP, it will have to terminate these services to physicians as of January 1, 2025.

88. The loss of participation in Integra's ACO would harm physicians in additional ways. Some physicians may choose to stop providing services entirely. Many physicians have come to rely on Integra's infrastructure and ability to bear the additional administrative and patient-care burdens of primary care practice, especially those in small independent private practices who cannot afford to employ their own quality improvement, care management, and pharmacy services.

89. Physicians would also experience technology-related burdens. Medicare requires sophisticated and onerous reporting through the Merit-based Incentive Payment System (MIPS). One benefit of ACO participation is that it exempts the physician from MIPS reporting and uses other reporting systems instead.

90. As of January 1, 2025, if Integra can no longer participate in MSSP, these physicians would have to shift to MIPS reporting. To enable this, entire technology infrastructures would have to change. This requires financial investments and time in new electronic health record

(EHR) systems and other computer databases. This would bring financial and operational challenges that would have a direct impact on the entire CNE health system and the private practices that are members of Integra if they chose to stay.

91. Physicians also count on their end-of-year shared savings payments to support their practices; if Integra cannot participate in MSSP, physicians will no longer have access to the shared savings payments that support their practice.

92. For patients, thousands of Medicare beneficiaries will no longer have access to a care manager through Integra. This will affect patients in primary care offices and those in hospitals who are being followed by the Integra transitions team. At any given time, Integra's care management and transitions teams support approximately 500-700 patients. Patients in Integra's home program, who have come to expect that Integra personnel will check on them at home, would be unable to access that service. For example, Integra provides in-home emergency paramedic care to assist patients when a primary care physician requests to, where possible, avoid an emergency-room visit. That program falls within a waiver. This would affect approximately 100 patients per month across Rhode Island who would no longer have access this service.

93. Medicare beneficiaries would also face imminent termination of other services as of January 1, 2025. For these remaining programs, even if Integra could find a way to provide certain of its services to Medicare beneficiaries in a lawful way, it could only provide those limited services at a loss because Integra would no longer have the ability to obtain shared savings payments that make these wraparound programs financially feasible. Patients would thus face the imminent loss of additional services to which they currently have access.

F. Judicial review of CMS's unlawful denial is available and essential.

94. After Integra received CMS's initial denial of its application, Integra promptly requested reconsideration review and submitted a supporting brief presenting CMS with its

arguments as to why CMS's denial of Integra's renewal application was unlawful. *See* Exhibits 2, 3. CMS has *still* not rendered a decision—and will not commit to rendering a decision before January 1, 2025. Judicial review is therefore available and essential to avoid serious irreparable harms.

1. Judicial review of CMS's denial is available under the Medicare Act.

a. Integra presented its claims to CMS, and exhaustion is excused.

95. Through 42 U.S.C. § 1395ii, the Medicare Act incorporates 42 U.S.C. § 405(h), which divests the district courts of federal-question jurisdiction to hear "any claim arising under" the Medicare statute and bars any "decision of the [Secretary of HHS]" from being judicially reviewed, "except as herein provided."[3]

96. The exception "herein provided" is created by 42 U.S.C. § 405(g). This provision, although not expressly incorporated into the Medicare statute under § 1395ii, has been treated by the Supreme Court as so incorporated. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 7-9 (2000); *Heckler v. Ringer*, 466 U.S. 602, 614-615 (1984). Section 405(g), as made applicable to the Medicare statute, authorizes any person to file a civil action, "after any final decision of the [Secretary of HHS] made after a hearing to which he was a party," to "obtain a review of such decision" in federal district court.

97. Section 405(g) imposes two requirements for obtaining judicial review of Medicare claims. The first requires that the plaintiff have "presented" the claim to the Secretary of HHS, a jurisdictional and non-waivable requirement. *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976); *Am.*

[3] The Supreme Court has held that "§ 1395ii does not apply § 405(h) where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (2000); *see also Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 681 n.12 (1986).

Hosp., 895 F.3d at 825. The second requirement is that the plaintiff must have exhausted the "administrative remedies prescribed by the Secretary" (*Mathews*, 424 U.S. at 328)—a "nonjurisdictional requirement" that "may be waived by the agency or excused by the courts." *Scott D. v. O'Malley*, 2024 WL 139145, at *1 n.1 (D. Me. 2024). *See also Mathew*, 424 U.S. at 328; *Heckler*, 466 U.S. at 614-615; *Shalala*, 529 U.S. at 24; *Justiniano v. Soc. Sec'y Admin.*, 876 F.3d 14, 24-27 (1st Cir. 2017).

98. The exhaustion doctrine is "intensely practical," and the "ultimate decision of whether to waive the exhaustion" considers numerous factors that assess whether a plaintiff's "interest in having a particular issue resolved promptly is so great that deference to the agency's judgment is inappropriate." *Justiniano*, 876 F.3d at 25 (quoting *Bowen v. City of New York*, 476 U.S. 467, 484 (1986); *Mathews*, 424 U.S. at 330). The Court considers whether the claim is "collateral," "the irreparable harm the plaintiff faces," and the "policies underlying exhaustion"—including interests in "accuracy, efficiency, agency autonomy and judicial economy." *Id.* (quoting *Doyle v. Sec'y of Health & Human Servs.*, 849 F.2d 296, 300 (1st Cir. 1998)).

99. These factors confirm that exhaustion should be excused for Integra's claim—which is that CMS's deeming rule cannot supplant the statutory eligibility requirement. As already described, Integra faces severe irreparable harm because of the unlawful denial. The policies underlying exhaustion would also not be served by requiring further agency process. With respect to accuracy, no "specialized administrative understanding" is necessary for the Court to evaluate the meaning of a statute, and a regulation's validity under it. *See Loper Bright*, 144 S. Ct. at 2268 ("delegating ultimate interpretive authority to agencies is simply not necessary to ensure that the resolution of statutory ambiguities is well informed by subject matter expertise. The better

presumption is therefore that Congress expects courts to do their ordinary job of interpreting statutes, with due respect for the views of the Executive Branch.").

100. Regarding efficiency and judicial economy, CMS has already taken 48 days to consider these issues and is yet to issue a decision; moreover, Integra's claim before this Court—regarding statutory meaning—is a task for a Court. Having this Court resolve that issue will not interrupt agency proceedings but will instead expedite them by resolving the issue this Court is meant to resolve. In the circumstances here, requiring Integra to wait for a reconsideration recommendation and then pursue an additional level of appeal to an independent CMS official—all the while suffering serious irreparable harms—is unwarranted, and exhaustion should be excused.

b. Jurisdiction-stripping does not apply.

101. During the reconsideration review process, CMS did not dispute the substance of Integra's arguments that its denial was unlawful. Instead, CMS contended only that 42 U.S.C. § 1395jjj(g) and 42 C.F.R. § 425.800 precluded Integra's request for administrative or judicial review of the denial of its application for the reasons raised. *See* Exhibit 4 at 3.

102. None of the Medicare Act's jurisdiction-stripping provisions apply to CMS's determination that Integra was ineligible for MSSP. The jurisdiction-stripping provisions in question carefully enumerate a number of situations for which there is no judicial or administrative review—but this case is not one of them. That this situation is not included in the detailed list of prohibited challenges proves Integra's point.

103. 42 U.S.C. § 1395jjj(g)(3) bars review over "the assignment of Medicare fee-for-service beneficiaries to an ACO under section (c)." But Integra is not challenging "the assignment" of any "beneficiar[y] to an ACO under section (c)." *Id.* Instead, Integra challenges CMS's

conclusion that Integra is ineligible to participate in MSSP under subsection (b). 42 U.S.C. § 13955jjj(b)(2)(D).

104. Here, the Court need not investigate or opine on the Secretary's beneficiary assignments *at all* to resolve Integra's challenge to the eligibility determination—Integra's claims accept the numbers resulting from CMS's assignment under subsection (c) and challenge the legality of CMS's eligibility determination based on those numbers.

105. Were there any doubt, the presumption of judicial review dictates that whenever a statute is "reasonably susceptible to divergent interpretation," courts must "adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review." *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 434 (1995). Courts have consistently applied the presumption in favor of judicial review "to questions concerning the preservation of federal-court jurisdiction" (*Kucana*, 558 U.S. at 251), including in the Medicare context. *See, e.g.*, *Bowen v. Mich. Academy of Family Physicians*, 476 U.S. 667, 678-689 (1986); *ACLA*, 931 F.3d at 1204; *Nat'l Assoc. Assoc. for Home Care & Hospice*, 2024 WL 1833811, at *7; *Loyola Univ. Med. Ctr. v. Becerra*, 728 F. Supp. 3d 128, 138-139 (D.D.C. 2024). The presumption of judicial review further confirms the conclusion that 42 U.S.C. § 1395jjj(b)(2)(D) and 42 C.F.R. § 425.800 do not present any bar to judicial review of Integra's claims.

2. Judicial review of CMS's delay is available under the Mandamus Act.

106. The Mandamus Act grants district courts jurisdiction over "any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361.

107. Jurisdiction under the Mandamus Act is available even in circumstances where federal-question jurisdiction or other statutory jurisdiction would be precluded by 42 U.S.C.

§ 405(h). *See McCuin v. Sec'y of Health & Human Servs.*, 817 F.2d 161, 166 (1st Cir. 1987); *see also Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 813 (D.C. Cir. 2001) ("joining the virtual unanimity of circuit courts" holding "that § 1361 jurisdiction is not barred" by Section 405(h)); *cf. Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 150, 167 (1st Cir. 20210 (assuming mandamus relief is available). Mandamus jurisdiction is particularly appropriate where the plaintiff brings a procedural challenge to CMS actions. *See McCuin*, 817 F.2d at 165; *Burnett v. Bowen*, 830 F.2d 731, 738 (7th Cir. 1987); *Lopez v. Heckler*, 725 F.2d 1489, 1507 (9th Cir. 1984), *vacated and remanded on other grounds*, 469 U.S. 1082 (1984); *Belles v. Schweiker*, 720 F.2d 509, 512-513 (8th Cir. 1983).

108. A writ of mandamus is available where "the plaintiff has exhausted all other avenues of relief and … the defendant owes the plaintiff a clear, nondiscretionary duty." *Camilo-Montoya v. United States*, 23 F.3d 394 (1st Cir. 1994).

109. Under the Administrative Procedure Act, federal agencies have a nondiscretionary duty to "proceed to conclude a matter presented to it" "within a reasonable time." 5 U.S.C. § 555(b).

110. Integra timely requested reconsideration review on October 30, 2024—within 15 days of CMS's denial—as required under 42 C.F.R. § 425.802(a)(1). Integra filed its supporting brief on November 12, and CMS filed its brief opposing Integra's reconsideration request on jurisdictional grounds on December 2.

111. It has now been more than two months since CMS's initial denial and 48 days since Integra requested reconsideration review. Yet a CMS reconsideration official still has not issued a recommendation. *See* 42 C.F.R. § 425.804(e).

112. A CMS reconsideration official has a nondiscretionary duty to issue a recommendation on reconsideration review. *See* 42 C.F.R. § 425.804(e) ("The reconsideration official will notify CMS and the ACO of his or her recommendation.").

113. Although there is no set timeframe by which the reconsideration official must issue the recommendation, the agency has a nondiscretionary duty to "conclude a matter presented to it" "within a reasonable time." 5 U.S.C. § 555(b).

114. In evaluating whether an agency has unreasonably delayed for purposes of mandamus relief, the Court considers "(1) [t]he length of time that has elapsed since the agency came under a duty to act, (2) [t]he reasonableness of the delay ... in the context of the statute authorizing the agency's action, (3) [t]he consequences of the agency's delay; and (4) [a]ny plea of administrative error, administrative inconvenience, practical difficulty in carrying out a legislative mandate, or need to prioritize in the face of limited resources." *City of Providence v. Barr*, 385 F. Supp. 3d 160, 164 (D.R.I. 2019), *aff'd*, 954 F.3d 23 (1st Cir. 2020).

115. These factors warrant mandamus relief requiring immediate issuance of a recommendation official decision.

116. First, Integra filed its request for reconsideration review on October 30, within 15 days of CMS's denial, at which point a reconsideration official became under a duty to issue a recommendation. It has now been 48 days since Integra requested reconsideration review.

117. Second, in context, this delay is unreasonable. That is because, in only 14 days, the new MSSP year will start, without Integra participating. Taking more than three times the length of time that Integra had to request reconsideration review in order to issue a reconsideration recommendation is unreasonable.

118. Third, the consequences of the agency's delay are enormous. As described above, Integra, its providers, and its patients will likely suffer immediate and irreparable harm if Integra's participation in MSSP is ended as of January 1, 2025. The agency's failure to make a decision imposes those consequences, whereas a favorable decision would avoid them.

119. Fourth, Integra is not aware of any administrative inconvenience, practical difficulty, or need to prioritize that would hinder the reconsideration official from issuing a recommendation immediately—and certainly none that would outweigh the strength of the other considerations.

120. Thus, in the alternative to reversing CMS's denial, the Court should, at the very least, issue a writ of mandamus compelling the immediate issuance of a reconsideration decision.

CLAIMS FOR RELIEF

COUNT I
The Secretary's Denial of Integra's Renewal Application Was Unlawful
(42 U.S.C. §§ 405(g), 1395ii; 5 U.S.C. § 706(2)(A), (C), (D), (E))

121. Integra realleges and incorporates by reference the allegations contained in the preceding paragraphs.

122. CMS's denial of Integra's MSSP renewal application for 2025 was an action of the Secretary for which Integra presented its claims and for which administrative exhaustion of remedies is excused. *See supra* ¶¶ 95-100; 42 U.S.C. §§ 1395ii, 405(g).

123. The Secretary's denial of Integra's MSSP renewal application for 2025 was contrary to the statutory minimum eligibility requirement, which requires only that an ACO "shall have at least 5,000" beneficiaries assigned to it. *See* 42 U.S.C. § 1395jjj(b)(2)(D).

124. If the Secretary's denial of Integra's MSSP renewal application for 2025 is not reversed, Integra will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II
Mandamus Act to Compel Agency Action

125. Integra realleges and incorporates by reference the allegations contained in the preceding paragraphs.

126. The Mandamus Act provides that "[t]he district courts shall have original jurisdiction of any action in the nature of mandamus to compel an officer . . . of the United States or any agency thereof to perform a duty owed to the plaintiff." 28 U.S.C. § 1361; *see also id.* § 1651 (All Writs Act, providing that courts "may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law").

127. A CMS regulation imposes a nondiscretionary duty for the reconsideration official to notify CMS and the ACO of his or her recommendation (42 C.F.R. § 425.804(e)), and the APA imposes a nondiscretionary obligation to act within a reasonable time (5 U.S.C. § 555). Yet CMS still has not acted.

128. The factors laid out by the Court in *City of Providence v. Barr*, 385 F. Supp. 3d 160, 164 (D.R.I. 2019), warrant relief.

129. The Court should therefore issue a writ of mandamus compelling CMS to act on Integra's request for reconsideration immediately.

PRAYER FOR RELIEF

WHEREFORE Integra respectfully requests that the Court enter judgment in its favor and against Defendants in the claims set forth above and respectfully requests that this Court:

a. issue a temporary restraining order and preliminary injunction staying the end of Integra's participation in MSSP until final judgment;

b. reverse the Secretary's denial of Integra's MSSP renewal application for 2025;

c. declare that the Secretary's denial of Integra's MSSP renewal application for 2025 was unlawful;

d. alternatively, issue a writ of mandamus compelling CMS's immediate issuance of a decision on Integra's request for reconsideration review; and

e. award Integra such further and additional relief as this Court deems just and proper.

Dated: December 18, 2024

Respectfully submitted,

INTEGRA COMMUNITY CARE NETWORK, LLC

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